SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,
Petitioner,

v.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

CLARK M. CLIFFORD
THOMAS D. FINNEY, JR.
THOMAS RICHARD SPRADLIN
CLIFFORD, WARNKE, GLASS, McILWAIN & FINNEY
815 Connecticut Avenue, N.W.
Washington, D. C. 20006

R. B. KADING, JR.
WILLIAM J. McKLVEEN
EBERLE, BERLIN, KADING, TURNBOW & GILLESPIE, CHARTERED
300 North Sixth Street
Post Office Box 1368
Boise, Idaho 83701

Counsel for Petitioner

October 29, 1974

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Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

The petitioner, WYETH LABORATORIES, prays that a writ of certiorari issue to review the opinion and judgment of the United States Court of Appeals for the Fifth Circuit rendered in these proceedings on July 31, 1974.

OPINION BELOW

The opinion of the Court of Appeals is reported as *Reyes* v. *Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974), and appears at Appendix A, *infra,* at pp. 2a, *et*

seq. The case was tried to a jury in the United States District Court for the Southern District of Texas, Brownsville Division, and that court did not render an opinion.

JURISDICTION

The judgment of the Court of Appeals was entered on July 31, 1974, Appendix A, *infra,* at p. 1a. This petition for certiorari was filed less than 90 days from the date aforesaid. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

1. Whether, by enactment of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301, *et seq.* (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. §§ 262, *et seq.* (1970), Congress has so pre-empted the field of law applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of this case solely on the basis of local tort law.

2. Whether the Court of Appeals contravened the public health policy of the State of Texas and of the United States and erred in its application of Texas law by holding, in the face of statutorily expressed public policy of Texas to the contrary and in disregard of the holding in the only Texas case in point, that under Texas law a manufacturer of a prescription drug, used to immunize large segments of the population against paralytic polio, is required to warn the ultimate consumer of the dangers of vaccination, even though admittedly adequate warnings have been given to the physician-administrators of the state public health facility dispensing the drug.

CONSTITUTIONAL, STATUTORY, AND FEDERAL REGULATIONS INVOLVED

The Public Health Service Act provides:

Sec. 351.

* * *

(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.

* * *

(g) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." [42 U.S.C. § 262(b), (g) (1970).]

The Federal Food, Drug, and Cosmetic Act provides at Sections 502 and 503:

"Sec. 502. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner

and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement." [21 U.S.C. § 352(a),(f) (1970).]

* * *

"Sec. 503. Exemptions in case of drugs and devices.

* * *

(b)(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection." [21 U.S.C. § 353(b) (1970).]

The provisions of 21 C.F.R. § 1.106 are in pertinent part as follows:

"§ 1.106 Drugs and devices; directions for use.

(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Di-

rections for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

* * *

(4) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, . . . contains: (i) Adequate information . . . under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended . . . ."

The language of 21 C.F.R. § 1.2 is as follows:

"§ 1.2 Labeling; label; definitions.

(a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) 'Label' means any display of written, printed, or graphic matter on the immediate con-

tainer of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity."

The relevant statute of the State is Vernon's Education Code of Texas, Section 2.09, which provides in part as follows:

"No person may be admitted to any elementary or secondary school or institution of higher education unless he has been immunized against . . . poliomyelitis . . . . except as provided in Subsection (c)."

The complete text of § 2.09 is reproduced in full at Appendix B, *infra*, at pp. 60a-61a.

STATEMENT OF THE CASE

On May 8, 1970, Anita Reyes, an 8-month-old infant, received a dose of trivalent oral polio vaccine at a State of Texas County Health Department Clinic in Hidalgo County, Mission, Texas. The vaccine was administered in the course of an epidemic as declared by the United States Government through the Center for Disease Control as a part of an epidemic control program conducted pursuant to the recommended policy of the Center for Disease Control in Atlanta, Georgia. Of the 33 cases of polio reported throughout the Nation during the year 1970, 22 occurred in Texas. All but one of these cases occurred in the Rio Grande Valley, where Anita Reyes resides, an area of concentrated Mexican-American population; and 1 out of every 3 of the Texas cases were in Hidalgo County. Center for Disease Control, *Annual Poliomyelitis Summary—1907*, at 1-4 (Sept. 30, 1971).

The vaccine Anita received was part of 400 vials manufactured and shipped by Petitioner in interstate commerce in accordance with Federal law and regulations. It was shipped by the Texas Department of Health in Austin, Texas, to the Hidalgo County Health Department, and had been purchased by the Texas Health Department under a competitive bid from Petitioner, Wyeth Laboratories. Wyeth Laboratories is a division of American Home Products Corporation and is the distribution outlet for Wyeth Laboratories, Inc., a wholly owned subsidiary of American Home Products.

Each vial of this vaccine contained a "package circular" detailing the dangers associated with taking the vaccine. The registered public health nurse at the Mission Health Clinic of the Hidalgo County Health Department had read the package insert. No warning of the inherent danger, characterized by the Court of Appeals as "statistically miniscule" (498 F.2d at 1274), was given by the public health nurse to Anita's mother. Approximately twenty days after she received the vaccine, it was determined that Anita had contracted Type I paralytic polio.

Respondent, Epifanio Reyes, filed suit individually, and as next friend of his minor daughter, Anita Reyes, against Petitioner in the Federal District Court for the Southern District of Texas, Brownsville Division, with jurisdiction based on diversity of citizenship. The jury concluded that Petitioner's vaccine was the cause of Anita's polio and rendered a verdict against Petitioner. On appeal, the United States Court of Appeals for the Fifth Circuit held Petitioner liable under Texas products liability law for failing to warn Anita's parents of the danger inherent in the vaccine.

REASONS FOR GRANTING THE WRIT

A. Congress Has So Pre-empted the Field of Law Applicable to Labeling of Prescription Biological Drug Products That It Was Error for the Courts Below to Dispose of the Case Solely on the Basis of Local Tort Law.

This case involves an important question of Federal supremacy which has never before been specifically considered by this Court. The manner in which this question is resolved will have a profound impact on public health care throughout our Nation, particularly on national programs of disease prevention.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a). A drug will also be deemed misbranded according to Section 502(f) if its labeling does not bear "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health . . . ." 21 U.S.C. § 352(f).

By Federal regulation, 21 C.F.R. § 1.106(a), the term "adequate directions for use" as used in Section 502(f) of the Act means "directions under which the layman can use a drug or device safely and for the purposes for which it is intended." These requirements, however, are not applicable to prescription drugs because of the provisions of Section 503 of the Act. That section exempts from the "directions for use" requirements of Section 502(f) any drug which is dispensed on the order of a practitioner licensed by law to administer such drug. This exemption of prescription drugs is further reflected in 21 C.F.R. § 1.106 (a)(1), which states that the "directions for use" re-

quirements shall not apply "to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner." The provisions of Section 502(a) prohibiting false or misleading labeling remain applicable to prescription drugs.

The foregoing provisions are not the only Federal laws regulating the labeling of biological drug products. The Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. §§ 262, *et seq.*, contains detailed requirements on the licensing, labeling, and marketing of any virus, serum, toxin, antitoxin, vaccine, or similar biological product in interstate commerce. Section 351 (g) provides explicitly, however, that: "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." 42 U.S.C. § 262(g).

It has not been and cannot be alleged that the labeling which Petitioner provided with its trivalent polio vaccine in this case was in any way false or misleading. It was the standard labeling developed with approval of Federal officials through long experience, and it was properly shipped in interstate commerce to the public health officials in charge of the immunization program out of which this case arose. That labeling, as required by Federal law, was directed to health professionals and contained all necessary directions and warnings. Because of the scientific and medical complexities surrounding this vaccine, as with any prescription drug product, adequate labeling could have been directed only to health professionals and not to the ultimate lay consumer.

The courts below would have the manufacturer attempt to provide some form of written information to the lay consumer regarding the use of this vaccine. Without question any such statement would amount to "labeling" under Federal law and regulations. That term is defined at Section 201(m) of the Act as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

The term is further explained by Federal regulation at 21 C.F.R. § 1.2:

> "§ 1.2 Labeling; label; definitions.
>
> (a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.
>
> (b) 'Label' means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity."

The court below has committed a fundamental error which, if not corrected, will have a profoundly adverse impact upon public health immunization programs in the future. In its attempt to equate the situation in this case with the sale of over-the-counter drugs, and draw therefrom a duty on the part of the manufacturer to provide labeling providing laymen with "adequate directions for use" of trivalent oral polio vaccine, the Court of Appeals' decision threatens to wreak havoc with our Nation's health care delivery system.

Erroneously, and contrary to Federal law, the Court of Appeals has assumed that the manufacturer, or anyone other than trained and licensed health professionals dealing directly with their patients, can provide "adequate directions for use" for prescription drug products which are meaningful to laymen, many of whom may be of limited educational background. This case does not involve the purchase of a common analgesic or an antacid at a local drug store. It involves the administration by public health authorities in an epidemic situation of a potent and complex vaccine properly manufactured and shipped in interstate commerce pursuant to Federal law.

The decision to conduct mass immunization in this case was made by public health authorities. The professional labeling accompanying the vaccine in question was made available by Petitioner to those authorities. The inherent risk involved in administering the vaccine was known to them. No representative of Petitioner was present during administration of the vaccine, and it would stretch the bounds of credibility to suggest that it should be otherwise.

The entire context of the Federal Food, Drug, and Cosmetic Act, as it concerns the labeling of prescription drug products, shows without question that Congress intended to pre-empt this area of interstate commerce. While the extension of Federal control into traditionally local matters is always a delicate exercise of legislative authority and requires accommodation between the needs of central control and the maintenance of local institutions, where the intent of Congress is clearly to pre-empt the field in matters regarding interstate commerce that intention must prevail. *Davies Warehouse Co.* v. *Bowles,* 321 U.S.

144 (1944). No one will question that where State and Federal laws do not overlap, a State's jurisdiction is unimpaired. *Id.; Algoma Plywood & Veneer Co.* v. *Wisconsin Employment Relations Board,* 336 U.S. 301 (1949). But as this Court has also noted in a related context involving the predecessor of the Federal Food, Drug, and Cosmetic Act:

> "... [I]t is equally well settled that the State may not, under the guise of exercising its police power or otherwise, impose burdens upon or discriminate against interstate commerce, nor may it enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the acts of Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution. *Texas & Pacific Ry. Co.* v. *Abilene Cotton Oil Co.,* 204 U.S. 426; *Northern Pacific Ry. Co.* v. *Washington,* 222 U.S. 370; *Southern Ry. Co.* v. *Reid,* 222 U.S. 424; *Second Employers' Liability Cases,* 223 U.S. 1; *Savage* v. *Jones, supra,* 533." *McDermott* v. *Wisconsin,* 228 U.S. 115, 131-132 (1913).

Therefore, where Congress has taken jurisdiction of a particular matter or type of controversy affecting interstate commerce, the States, through their courts, may be precluded from adjudging the controversy and extending their own forms of relief. *Garner* v. *Teamsters Union,* 346 U.S. 485 (1953).

In the situation now at hand the purpose of Congress is clear and manifest. The labeling of prescription drug products shipped in interstate commerce is subject entirely to Federal law and regulation, and the States are without power to impose contrary restraints in this area. When the manufacturer of a prescription drug

product has complied fully with the provisions of Federal law regarding the labeling of that product, he has completed his obligation to the public. Indeed, he should have no other obligation to the public with regard to prescription drug labeling than to comply with Federal law, whether that obligation be asserted in the form of criminal sanctions or civil or tort liability. Moreover, throughout the Federal statutes and regulations on this subject there is an inherent recognition of the sanctity to be accorded the doctor-patient relationship. No drug manufacturer is required or even allowed under Federal law to interpose himself between doctor and patient.

The decision of the Court of Appeals below, if left standing, would not only violate Federal policy as promulgated by Congress and the Secretary of Health, Education, and Welfare but would also inevitably breed a new form of liability suit brought by individuals against drug manufacturers based on unavoidable injuries due to inherent risks in taking prescription medication on the advice of health professionals. Such a result would alter in a fundamental way the health care delivery system in this Nation. Manufacturers, not health professionals, would be ultimately responsible for the administration of prescription drugs to individual patients.

The effect of the Court of Appeals' decision would be to remove the public health physician in particular from the relationship between the patients of a public health clinic and the manufacturers whose drugs are used to further the goals of such an institution. To the class of persons dependent upon the services provided by a public health clinic, the lower court's decision would have a devastating impact. These per-

sons would be faced with a choice which they are unprepared to make and which would be made for them if they had the financial resources to seek health care from a private physician. This is true because, as Petitioner has repeatedly emphasized, in the administration of polio vaccine there is no basis for the individualized medical judgment on which the court below rests its decision. This fact was either ignored or never understood by the Court of Appeals. For the Nation as a whole, but particularly for large agricultural states such as Texas with a significant number of poorly educated migrant laborers among whom the incidence of communicable diseases such as polio is tragically high, the lower court's conclusion that public health authorities cannot play a meaningful role in administering prescription drugs used in immunization programs will have serious repercussions because of the increased likelihood of communicable disease epidemics. This is especially true should manufacturers of polio vaccine be forced to discontinue its sale to public health institutions because of the problem of insuring that adequate warnings are given. The Court of Appeals' reference to cost-benefit analysis cuts both ways. Also, the lower court's suggestion that the manufacturer's loss "be passed on to the public in the form of price increases to [its] customers," 498 F.2d at 1294, is an unrealistic assessment. Public health institutions are by far the largest-volume purchasers of Petitioner's vaccine, and they are financed by State and Federal governments which have neither the intention nor the authority to become the manufacturer's insurers.

The assumption of necessary and unavoidable risk in the case of administration of any potent prescription

drug is a medical judgment to be made by the health professional in dealing with his patient. To place that risk at the door of drug manufacturers will, among other things, have a chilling effect on their ability to cooperate with public health officials in epidemic situations such as that in this case. It is Federal policy to leave the decision on administration of drugs similar to the vaccine here to individual health professionals in the context of their own relationships with their patients—even in public health situations. That policy is clearly seen in the Federal statutes and regulations. It is a policy which the decisions below would destroy.

B. The Decision of the Court of Appeals Is in Conflict with Applicable Texas Law and Federal and State Public Policy on the Important Question of Whether the Manufacturer of a Prescription Drug Has a Duty to Warn the Ultimate Consumer of Possible Risks Involved in Taking the Drug.

This case merits review because of the significant public health ramifications which will flow from the lower court's holding that the manufacturer of a prescription drug, administered in the course of a Federally approved State program designed to immunize segments of the population against a highly communicable disease, is required to warn the ultimate consumer of the danger inherent in the drug, even though an adequate warning has already been given to the physicians in charge of the public health facility which dispenses the drug. The importance of this issue cannot be overstressed, since it is certain that the impact on future operations and decisions of public health authorities—both State and Federal— will be disruptive not only with respect to the administration of polio vaccine, but also with respect to other drugs administered in public health clinics or in the course of publicly sponsored mass immunization programs.

The Court of Appeals failed to follow applicable Texas law, and ignored the very strong public policy of the State of Texas in preventing the spread of communicable disease. Review by this Court is needed to correct this misapplication of State law, and to avoid the serious adverse effects which it is certain to produce.

There can be no doubt that Texas has a strong interest in preventing the spread of communicable diseases. In order to implement this policy, Texas law requires that students be immunized against certain communicable diseases, including poliomyelitis. Vernon's Education Code of Texas § 2.09 (1971). [See Appendix B, *infra*, pp. 60a-61a.]

The success of such programs of immunization in virtually eliminating epidemics of poliomyelitis is well known. As the Court of Appeals recognized, much of the credit for the elimination of polio from the United States is due to the combined efforts of Federal and State public health authorities and the manufacturers of polio vaccine. 498 F.2d at 1270. Substantial participation in such immunization programs by the Federal Government indicates the national importance of these efforts.[1] The current policy of the Federal Gov-

[1] For the past 10 years, the United States Public Health Service, an agency of the Department of Health, Education, and Welfare, has advocated the use of oral polio vaccines to combat the threat of poliomyelitis and has played a substantial role in encouraging mass immunization programs. *See* Report of the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccines, 190 A.M.A. Journal at 49-51 (October 1964). This policy has been frequently reiterated. *See, e.g.*, 16 A.M.A. Journal (August 1967); 18 A.M.A. Journal (October 1969); 21 A.M.A. Journal (June 1972). In line with this Federal policy the United States Public Health Service through the Center for Disease Control in Atlanta, Georgia, has been an active participant in watching for

ernment is manifested by a recent proclamation in which the President of the United States urged "all parents, educators, and medical personnel to exert renewed efforts during this week and throughout the year to immunize every American child against diseases for which vaccines are available." Presidential Proclamation 4329, *Immunization Action Week 1974,* October 21, 1974 [39 Fed. Reg. 37629 (Oct. 23, 1974); See Appendix C, *infra,* p. 62a.]

In an epidemic situation the public health physician has only one choice to halt the spread of communicable disease. That choice is mass immunization. Under the Court of Appeals' decision below the manufacturer of the prescription drug to be used in the immunization program would be required to interfere with that choice by carrying a warning to the ultimate consumer. The effect of that holding would be to undermine the ability of public health physicians to act decisively and effectively to control threatened epidemics, such as the situation which existed in Hidalgo County in 1970.

The polio vaccine administered here was not defectively manufactured. It was "exactly what its makers and the Texas public health authorities intended it to be." 498 F.2d at 1273. Even so, there remained the chance—established statistically at ranges from 1 in 1 million to 1 in 16 million— that one ingesting the vac-

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and in helping state and local authorities control outbreaks of poliomyelitis. (For examples of this participation refer to the official publication of the Center for Disease Control, Morbidity and Mortality Weekly Report, for the following weeks: July 28, 1963 (Pennsylvania); August 2, 1963 (Walker County, Alabama); April 3, 1965 (Pinal County, Arizona); May 22, 1965 (Scotts Bluff, Nebraska); June 26, 1965 (Arizona); July 2, 1966 (Texas); August 13, 1966 (Texas); February 24, 1968 (Hidalgo County, Texas); May 30, 1970, (Hidalgo County, Texas); and September 19, 1970 (San Antonio, Texas).)

cine would contract polio.[2] Unlike most other prescription drugs, however, it cannot be determined by a physician on the basis of an individual's medical history, physical condition, or from a medical examination whether a particular person is susceptible to contracting polio from ingestion of this vaccine. This is especially true of infants and young children. Thus, the medical judgment involved can be made just as intelligently on a generic basis by public health physicians as it can on an individual basis by a private physician, the patient, or the patient's parents. A warning of some sort by the manufacturer to the ultimate consumer would not provide for a more informed choice, but would merely impede the efforts of public health authorities to prevent the outbreak of an epidemic.

Petitioner's liability is grounded on its failure to warn Anita's mother of the statistical probabilities involved in her daughter's taking the vaccine. In the Fifth Circuit's view, the necessity for such a warning stems from the unavoidably unsafe nature of the vaccine and the need when dealing with such a drug for "an individualized medical judgment that this treatment or medication is necessary and desirable for this patient." 498 F.2d at 1295. To hold Petitioner strictly liable in tort, the court necessarily concluded that an individualized medical judgment was necessary and that this func-

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[2] Generally, these statistics were compiled by epidemiologists. Epidemiology is a specialized field of medicine dealing with public health, which is based on the observation of disease and thereafter, by statistical methods, trying to arrive at a conclusion as to the possible source of the disease. 498 F.2d at 1271 n. 3. The statement in the text does not mean that one of every million persons who takes the vaccine will contract polio; it means that within the ranges given, it is statistically compatible with the possibility that the vaccine caused the illness.

tion was not performed by the State's public health physicians. This two-pronged conclusion is the foundation for the court's decision because of the rule "that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* at 1276.

Although Petitioner's vaccine was conceded to be a prescription drug, the court avoided the prescription drug rule by reasoning, in essence, that it would not apply unless there was a face-to-face meeting of patient and physician. Absent such a meeting the principles applicable to the sale of over-the-counter drugs, which require a warning to the ultimate consumer, govern the manufacturer's discharge of its duty. *Id.* at 1276. Considered against the backdrop of public health policy, the Fifth Circuit's all-or-nothing approach not only threatens the effectiveness of the State's program to prevent the spread of communicable disease but also represents an egregious misapplication of Texas products liability law.

The Circuit Court's misapplication of Texas law is highlighted by its improper treatment of the only Texas case in point on the issue whether Petitioner's warning to the public health authorities was sufficient to discharge its duty. In *Gravis* v. *Parke-Davis & Co.*, 502 S.W.2d 863 (Tex.Civ.App.—Corpus Christi, 1973), the court was concerned with a prescription drug manufacturer's duty to warn the ultimate consumer of the dangers of a particular drug.

> "We hold that it is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician *or other authorized persons.* The

> entire system of drug distribution in America is set up so as to place the responsibility for distribution and use upon professional people. The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry." 502 S.W.2d at 870. (Emphasis added.)

Obviously, the approach taken by the court below is directly contrary to the holding in *Gravis*. The *Gravis* court rejected the approach taken by the Fifth Circuit by explicitly recognizing that the central question is whether a "physician or other authorized [person]" has made the decision that a particular drug should be used. A Texas court faced with the circumstances of this case would have held as a matter of law, based on *Gravis*, that the warning to the public health physicians discharged Petitioner's duty to warn anyone else.

A different panel of the Fifth Circuit, applying Texas law, recently held that a Texas physician is not required to inform his patient of all the risks involved in the treatment offered. He must only act as would a reasonable medical practitioner in the same circumstances. *Karp* v. *Cooley*, 493 F.2d 408 (5th Cir. 1974. *See also*, *Wilson* v. *Scott*, 412 S.W.2d 299, 301 (Tex. 1967); *Gravis* v. *Parke-Davis & Co.*, *supra*, 502 S.W.2d at 870.

The underlying rationale of *Karp* is contrary to the approach taken by the Fifth Circuit in this case. Petitioner provided a complete and adequate warning to the appropriate public health officials. These officials,

having determined that a polio epidemic was in progress in the Rio Grande Valley, and acting in accordance with Federal and State policy, determined that every effort should be made to immunize all persons. There can be no doubt that their action complied with the standard outlined in *Karp* as measured by the local and nationwide practices of public health physicians.

The lower court's attempt to distinguish the vaccine involved in this case from other prescription drugs which require no warning to the ultimate consumer is based on the absence of a "prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." 498 F.2d 1276. The assessment of risk by public health physicians, and their decision not to warn each recipient is in accord with the standards set in *Karp,* and represents the same type of judgment that a prescribing physician would make. Furthermore, the court below conceded that an individual prescribing physician would be unable to do any more than the State authorities have done in treating a particular patient, since, as the court noted, ". . . the risk appears to be distributed evenly among that substantial segment of the population that is not naturally immune to polio. This is so because the behavior of polio virus in those who contract the disease seems to suggest more a reversion to virulence by the virus than a sensitivity in the vaccine." *Id.* at 1279. Accordingly, an individualized examination of each patient would in no way lessen the risk involved.

Thus, Petitioner, by providing an adequate warning to Texas public health authorities, fully discharged any duty it had under Texas law, as well as Federal law, since the State's authorities could and did func-

tion as a "learned intermediary" whose judgment relieved the manufacturer of a duty to warn the ultimate consumer directly.

In reaching its decision, the Court of Appeals relied almost exclusively throughout its opinion on the reasoning of *Davis* v. *Wyeth*, 399 F.2d 121 (9th Cir. 1968), which also involved a plaintiff who allegedly contracted polio from Petitioner's vaccine. On the facts of this case, the court's reliance on *Davis*, which involved an application of Montana Law, cannot be reconciled with the applicable Texas authorities, or with the strong public policy of Texas in favor of immunizing all the children of the State against polio.

In *Davis* the vaccine was given in 1963 to a 39-year-old man in a nonepidemic environment in the course of a mass immunization program conducted by the local medical society with Petitioner's cooperation. Because of unusual circumstances the vaccine was administered by a pharmacist, rather than by a registered public health nurse or physician. The *Davis* court characterized the vaccine as "new and experimental," as indeed it may have been in 1963, and also observed:

> "A fact sheet put out by [Wyeth] and contained in the book it supplied to clinics was published prior to the Surgeon General's Report and represented the vaccine as completely safe for all ages. A collection of news clippings from Idaho newspapers introduced in evidence by [Davis] shows not only a complete lack of warning but assurances that the vaccine was safe for all." 399 F.2d at 125.

The *Davis* court based its decision, then, on the theory that no adequate warning was given to anyone. This is crucial because there was some evidence that an

adult of that plaintiff's age stood a statistically higher risk of contracting polio than would a child. On these facts, the Ninth Circuit reversed a jury verdict for the defendant, holding that the District Court erred in failing to instruct the jury on the warning issue.

Petitioner does not contend that it has no duty to warn. Rather, it asserts now, as it has continuously (see 498 F.2d at 1275), that its duty was fulfilled. The warning present with each vial of vaccine contains cautionary language regarding administration of the vaccine and no contention has been made that this warning is inadequate. Moreover, the warning in this case was given to physicians in charge of a State's public health program—physicians eminently familiar with the needs of those the program would serve, and to the public health nurse who administered the vaccine. Finally, the vaccine here was given to an 8-month-old child, in an epidemic environment, with the undisputed fact being that children of tender years are most susceptible to polio. These are not distinctions without differences, for they thoroughly undermine the lower court's mechanistic reliance on *Davis*. Petitioner submits that a Texas court would not have regarded *Davis* as controlling on the basis of these factual differences and in view of the State's strong public policy in favor of universal immunization for its children.

That the Court of Appeals erred, to a degree warranting review by this Court, in relying so heavily on *Davis* and in failing to accord any weight to the applicable decisions interpreting Texas law is apparent when the factual context in which the vaccine was administered here is considered.

The court either failed to consider or attached too little significance to the type of health institution at

which Anita Reyes received the polio vaccine. The Mission Health Clinic in Mission, Texas, is run by the Hidalgo County Health Department, which in turn is an arm of the Texas State Department of Health. It is one of many such institutions operating throughout the State of Texas and across the Nation. The clinic is staffed by two registered public health nurses, there being no physician there on a fulltime basis. The crucial decisions are made by medical doctors at the local, county and State level. One of the primary functions of these local public health clinics is to provide health care for those who cannot afford a private physician. Large segments of the population receive communicable disease vaccines, including polio vaccine, free of charge to the recipient at these clinics. As a practical matter, these innoculations against the more common communicable diseases may well be the only health care received by a significant portion of the population.

The need for such services in Texas is obvious. As we have previously mentioned, of the 33 cases of polio reported nationwide in 1970, 22 occurred in Texas, with all but 1 of the cases occurring in an area of concentrated Mexican-American population and the vast majority in the Rio Grande Valley area where Anita Reyes resides. In fact, 7 of the 22 Texas cases were from Hidalgo County. Center for Disease Control, *Annual Poliomyelitis Summary—1970*, at 1-4 (Sept. 30, 1971). We need say no more to illustrate that the problem is not hypothetical or a matter of conjecture—it is an ever-present concern of public health authorities.[3]

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[3] On September 30, 1974, while counsel for Wyeth was preparing this petition, an Associated Press article appeared on the front page of the *Idaho Statesman* in which the Center for Disease Con-

In summary, Petitioner submits that had the issue been submitted to the Texas courts, the State's public policy in favor of polio immunization combined with the admittedly adequate warning to the appropriate State public health authorities would have produced a holding that the manufacturer of this prescription drug was not required, to provide the ultimate consumer with some form of "labeling" about the drug which would include information on the statistical danger of contracting polio by ingesting the vaccine. "[I]t is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician or other authorized persons." *Gravis* v. *Parke-Davis & Co., supra,* 502 S.W.2d at 870; *see Karp* v. *Cooley, supra,* 493 F.2d at 420. Texas, by enacting its statute mandating immunization of children against poliomyelitis, has made a policy judgment which the Court of Appeals ignored. A Texas court would have recognized this policy, would have examined the circumstances in which the vaccine was administered, and then would have held as a matter of law that the warning to the public health physicians discharged Petitioner's duty.

It is apparent that the Court of Appeals failed in its duty to construe, interpret, and apply Texas law as would a Texas court. This error can only be corrected if this Court grants Petitioner's writ of certiorari.

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trol in Atlanta, Georgia, a division of the Department of Health, Education, and Welfare, warned that nationwide epidemics of childhood diseases could still erupt. Figures released by the CDC indicated that immunization levels for polio for 1-4 year-old children dropped in 1973 to a low of 60.4 percent, compared to 84.0 percent in 1963. *See also, New York Times,* Oct. 10, 1974, at 10, col. 3.

CONCLUSION

For the reasons stated, a writ of certiorari should be granted to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

CLARK M. CLIFFORD
THOMAS D. FINNEY, JR.
THOMAS RICHARD SPRADLIN
CLIFFORD, WARNKE, GLASS, McILWAIN & FINNEY
815 Connecticut Avenue, N.W.
Washington, D. C. 20006

R. B. KADING, JR.
WILLIAM J. McKLVEEN
EBERLE, BERLIN, KADING, TURNBOW & GILLESPIE, CHARTERED
300 North Sixth Street
Post Office Box 1368
Boise, Idaho 83701

Counsel for Petitioner

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